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(71) Applicant: Parisi, Tullo
12344 Oak Knoll Road Suite B
Poway California 92064(US)

Applicant: Massengill, Richard Kemp
16766 Bernardo Center Suite 209
San Diego California 92128(US)

(72) Inventor: Parisi, Tullo
12344 Oak Knoll Road Suite B
Poway California 92064(US)
Inventor: Massengill, Richard Kemp
16766 Bernardo Center Suite 209
San Diego California 92128(US)

(74) Representative: Hulse, Thomas Arnold et al
Hulse & Co. Cavendish Buildings West Street
Sheffield S1 1ZZ(GB)

(54) Liposuction procedure with ultrasonic probe.

(57) A method of removing animal fatty tissue includes inserting an ultrasonic aspirating probe (10) into the body in the area of the fatty tissue between the flesh, including blood vessels and arteries, and the muscle. The probe (10) is ultrasonically vibrated at high frequencies and low amplitudes creating localized tissue separation and frictional heat. This heat causes the fatty tissue surrounding the probe (10) to melt. The probe (10) is specially adapted to provide a localized flow of irrigating fluid. This fluid serves to emulsify the melted and separated fat. The emulsified fat is then aspirated through specially designed orifices from the body using suction.

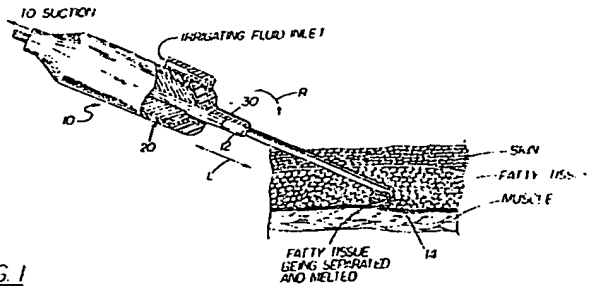

FIG. 1

EP 0 331 313 A1

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LIPOSUCTION PROCEDURE WITH ULTRASONIC PROBE

This invention concerns a method of liposuction. Liposuction is a type of cosmetic surgery whereby undesirable accumulations of body fat are removed by suction. Liposuction is becoming increasingly popular, and is seen by many as a way to quickly remove undesirable body fat which may or may not be removed by the more traditional ways of diet and exercise.

Liposuction is rapidly gaining popularity because it provides an easy way to remove unwanted body fat. Generally, dieting serves only to reduce the size of fat cells, not their number. It is this fact which makes maintaining one's lowered body weight after dieting so difficult. Liposuction takes an alternative approach by physically removing the fat cells. Additionally, liposuction serves as a means for reducing the bulk in areas which could not be reduced by dieting and exercise. For example, it is not unusual to perform liposuction on an individual's eyelids or under the eyes, and at other localized areas on the face.

The traditional liposuction techniques include the use of a cannula connected to an external source of suction. In use, an incision is made in the area of the fat desired to be removed, the cannula inserted in the area (between the flesh and muscle), and the suction begun. The fat is then sucked out of the body. This basic method has its disadvantages, however, because fat is relatively difficult to separate from the surrounding tissue by simply the sucking action. There is a tendency for the entry orifice on the cannula to clog with the fat. In other words, it is difficult to keep the operation going without stopping to clean out the cannula orifice. Normally, the surgeon attempts to compensate for this problem by manually moving the cannula within the cavity, and even periodically withdrawing it to force through the fat that is stuck in the orifice. Further, the surgeon must be careful not be allow to suction to pull and remove desirable tissues, such as the flesh, muscle, blood vessels and the like. Therefore, the speed, safety and effectiveness of the current liposuction method leaves much to be desired and a successful operation depends on the practitioner's exceptional skill.

It is known to use ultrasonically vibrating/aspirating probes in the fields of cataract surgery and dental cleaning. There have also been suggestions of use of these probes in removing other types of relatively hard body tissues, such as brain tumors.

In each case, the intention is to introduce the vibrating probe into the area of material desired to be removed, and use the ultrasonic vibrations to physically fracture or cut the material. Such a procedure lends itself well to cataract surgery, for example, because the cataract desired to be removed is relatively hard and capable to bring fractured.

Representative patents in this field include U.S. Patent 4, 169,984. Also U.S. Patent 4,515,583 and U.S. Patent 4,531,934 teach the same basic approach of an ultrasonic surgical probe with aspirator used to fragment and remove undesirable cataract or other hard tissue. Use of ultrasonics in cataract surgery is, in fact, widely regarded as safe and efective.

A need exists for a method of performing liposuction which removes the unwanted relatively soft, fatty tissue in much the same manner as utilizing the cannula, yet which is more effective and may be carried out without interruption. Such a method would greatly assist those practicing liposuction to remove unwanted fatty tissue more quickly and reliably.

Accordingly, it is an object of the present invention to provide a method for aspirating animal fatty tissue utilizing an ultrasonic probe.

Another object of the present invention is to provide a method for aspirating animal fatty tissue to emulsifying the tissue and then removing it by use of externally provided suction.

Still another object of the present invention is to provide a method for aspirating animal fatty tissue without damage to or removal of flesh tissue, blodd vessels, and the like.

Yet another object of the present invention is to provide a method for aspirating animal fatty tissue utilizing ultrasonic vibrations to create more efficient tissue separation, and even localised tissue melting through frictional heat, thereby allowing highly efficient removal.

According to the present invention, a method of removing animal fatty tissue from a patient in vivo comprises the steps of: inserting an aspirating probe into the body in an area between the flesh and the muscle in the area of said fatty tissue;
ultrasonically vibrating the probe at substantially high frequencies and low amplitudes;
irrigating the area surrounding the probe;
emulsifying said fatty tissue;
aspirating the emulsified fatty tissue by applying suction;
the method being characterised by the steps of:
creating localised tissue separation;
creating localised frictional heating; and
melting at least some of some fatty tissue by said localised heat.

It should be recognised that although this method can be used on all animals, it is intended

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to be utilised primarily on humans.

The method of the present invention provides for inserting the tip of an ultrasonic aspirating probe into the area of the fatty tissue. One such probe, which can be readily modified for this procedure, is that disclosed in United States Patent 4,169,984 and mentioned above. The probe includes a housing containing an internal piezoelectric crystal transducer assembly for creating ultrasonic vibrations. A hollow insert with a probe tip is threadedly engaged in the transducer assembly of the probe.

To perform the method of the present invention, the probe tip is what must be modified. The choice of the tip depends upon the precise nature of the liposuction procedure being performed. Three alternative tips are illustrated and a selection is made based on the particular type of body area being treated. A rounded, bullet-shaped tip with a closed end and a single elongated entry orifice is the standard configuration and may be used for a majority of body area. A tip with a portion of the end open is utilized for localised entry and fat removal, such as in areas around the smaller body appendages; whereas, a tip having multiple entry orifices is provided for unobstructed and flatter areas, such as the thighs and buttocks, where the probe tip may be extended into the fatty area for a substantial distance.

Additionally, an irrigation sleeve is provided which partially surrounds the probe tip and provides a localised flow of irrigating solution to the body cavity where the fat is being removed. The irrigation sleeve snaps onto the probe and is readily removable.

In an alternative method, the irrigating solution is introduced directly through the probe tip. Obviously, in this alternative method, the probe operates by cycling between aspirating and irrigating modes. The choice of which method to use depends on the type and location of the operation being performed.

During operation, the surgeon determines the location and extent of fatty tissue to be removed. An incision is made large enough to permit passage of the probe tip. The tip is guided through the skin and flesh layers, which include the blood vessels, and into the layer of fatty tissue below.

The probe tip is preferably vibrated at 40,000 cycles per second at an amplitude of 2 mil. This high frequency, low amplitude vibration serves to separate the fatty tissue efficiently and safely and create localised heat through frictional contact. This localised frictional heat serves to assist in the removal by physically melting a thin layer of surrounding fatty tissue.

The separated and melted fatty tissue is preferably emulsified by application of the saline irrigating solution from the tip of the irrigation sleeve. The emulsified solution is then aspirated by use of an external suction. It should be pointed out that the intensity of the vibration and localised heat applied can be varied by adjusting the frequencies and amplitudes of vibration.

The method of the present invention results in liposuction procedures significantly more reliable than were possible using the traditional non-vibrating cannula method. This is because the ultrasonic probe tip operating in this manner does not disturb any of the surrounding tissue with which it becomes into contact. By removing only the fatty tissue and leaving the other tissue including the blood vessels intact, a safer surgical procedure results. As a reault, healing time is also significantly reduced.

Reference will not be made in detail to the method of the invention at present preferred and which is illustrated by the accompanying drawings by way of example only.

Figure 1 is a cut-away view of an ultrasonic aspirating probe shown inserted into the fatty tissue cavity of a body between the skin/flesh layers and the muscle layer and performing the method of the invention;

Figure 2 is a cross-sectional view of the area of the body as shown in Figure 1 with the fat having been removed by the method to form a slimmer profile;

Figure 3 is a cut-away view of a complete ultrasonic probe suitable for use in carrying out the method and additionally including an irrigation sleeve;

Figure 4 is a cross-sectional view taken along section line 4-4 of Figure 3;

Figure 5 is a perspective view of a preferred, general purpose insert for use with the probe of Figure 4 to perform the method of the present invention and with an extra detailed plan view of the tip illustrating the entry orifice; and

Figure 6 is a composite showing of two additional tips, including for each a plan and side view illustrating alternative orifice configurations.

Reference is now made to Figures 1 and 3 showing an ultrasonic aspirating probe 10 ideally suited for carrying out the method of the present invention. The probe 10 includes a hollow insert 12 having a probe tip 14, and an internal ultrasonic transducer assembly 20, which includes piezoelectric crystals 22, 24 which are securely retained within body member 26, 28. As is known in the art, an alternating voltage of ultrasonic frequency is applied to the transducer assembly 20. This causes the crystals 22, 24 to vibrate ultrasonically. This vibration is transferred to the hollow insert 12 and the probe tip 14. For a more detailed review of the

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transducer assembly and how it operates to produce ultrasonic vibration, reference is made to U.S. Patent 4,169,984, mentioned above.

To perform the method of the present invention, the probe tip 14 must be modified from the probe tips commonly known and used by practitioners of the liposuction art. As shown in Figures 5 and 6, various probe tips 14, 16 and 18 are provided, the choice of which depends upon the precise nature of the liposuction procedure being performed. More specifically, the choice of which tip 14, 16 or 18 to use depends upon the particular type of body area being treated. Figure 5 shows an insert 12 having a rounded bullet-shaped tip 14, which a closed end and a single elongated entry orifice. From experimentation this probe tip 14 has been established as the stadard configuration, and it is used for the majority of body areas.

Figure 6 shows two alternative probe tip configurations. Probe tip 16 is a bullet-shaped tip having a portion of the end open. Probe tip 16 is used to remove fat in tight areas, such as around the small apendages of the body. Probe tip 18 having multiple entry orifices is used in body areas providing clear access over a wider area, and is particularly useful in areas, such as the thighs and buttocks, where the probe tip 18 may be extended into the fatty area for a substantial distance. This allows faster fatty tissue removal, resulting in quicker, more efficient liposucion operations.

An irrigation sleeve 30 is provided to direct a flow of irrigating solution directly to the probe tip 14 (see Figures 1, 3 and 4). The sleeve 30 partially surrounds the insert 12 including the probe tip 14. Advantageously, the sleeve 30 snaps on to the probe 10 and is readily removable. Because the sleeve 30 is non-vibrating and closely surrounds the insert 12 (see Figure 4), sleeve 30 serves as a thermal insulator. In other words, the tissues found in the areas above the sleeve 30 are protected from the ultrasonically created heat. In this way, the ultrasonic liposuction may be performed in areas very close to the skin, without damaging this delicate tissue.

During operation, the surgeon determines the location and extent of fatty tissue to be removed. Based on this initial determination, the surgeon next chooses, and installs within probe 10, the hollow insert 12 having the appropriate probe tip 14, 16 or 18. An incision is made, and the tip 14, 16 or 18 is guided through the skin and flesh layers, which include the blood vessels, and into the layer of fatty tissue below.

In the preferred method, the probe 10 is vibrated at approximately 40,000 cycles per second at an amplitude of about 2 mil. This high frequecy, low amplitude vibration serves to efficiently and safely separate the fatty tissue and create localised heat through frictional contact. Advantageously, this localised frictional heat serves to assist in the removal by physically melting a thin layer of surrounding fatty tissue.

During use, the probe 10 is moved in a back and forth and twisting manner as is indicated in Figure 1, by arrows L and R respectively. This motion helps to further separate the fatty tissue, and generally speeds up the operation.

The separated and melted fatty tissue is emulsified in the preferred embodiment by application of a saline irrigating solution from the tip of the irrigating sleeve 30. The emulsified solution is then aspirated by use of an external suction source. The intensity of the vibrations and localised heat applied can be varied by adjusting the frequencies and amplitudes of ultrasonic vibration. This allows the surgeon to fine tune the liposuction procedure to each individual situation.

As shown in Figure 2, using the method of the present invention removes the fatty tissue and its associated bulk, leaving the desired thinner profile appearance. The choice of how much fatty tissue to remove depends on the final appearance disired by the patient. The surgeon can remove as little, or as much fatty tissue as necessay, to achieve the desired final appearance.

The method of the present invention results in liposuction procedures significantly more reliable than were possible using the traditional non-vibrating cannula method. This is because the ultrasonic probe 10 aspirates only the undesirable fatty tissue while leaving the desirable tissue such as blood vessels, muscle and the like intact. Advantageously, this provides a safer surgical procedure characterised by reduced healing times.

The vibration constantly and effectivley shakes the separated fatty tissues at the entry orifice(s) to allow easier entry into the tip 14, 16 or 18 and prevent clogging. In this manner the process is substantially accelerated providing greater efficiency and further lessening the trauma to the patient. Also the heat generated to assist in melting some of the fat tends to be focused in the area of the entry orifice(s). The additional heat is generated along the remaining length of the exposed insert 12 thereby providing the relatively thin layer of melted fat. A roughened texture on the insert may provide additional heat generation thereby allowing the surgeon to further fine tune the procedure.

Claims

1. A method of removing animal fatty tissue from a patient in vivo comprising the steps of:
inserting an aspirating probe (10) into the body in an area between the flesh and the muscle in the

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area of said fatty tissue;
ultrasonically vibrating the probe (10) at substantially high frequencies and low amplitudes;
irrigating the area surrounding the probe;
emulsifying said fatty tissue;
aspirating the emulsified fatty tissue by applying suction;
the method being characterised by the steps of:
creating localised tissue separation;
creating localized frictional heat; and
melting at least some of some fatty tissue by said localized heat.

2. A method as in Claim 1, characterised in that adjustment is provided for the amplitude any frequency of the ultrasonic vibrations to vary the intensity of the localized heat.

3. A method as in Claim 1 or Claim 2, characterised in that placement of the probe (10) is in the area substantialy below the patient's blood vessels.

4. A method as in any one of Claims 1 or 3, characterised in that there is provided forcusing of said heat adjacent a probe tip (14) having a rounded, closed end and at least one entry orifice.

5. A method as in any one of Claims 1 or 3, characterised in that there is provided forcusing of said heat adjacent a probe tip (16) having a rounded, partially closed and partially open end.

6. A method as in any one of Claims 1 to 3, characterised in that there is provided focusing of said heat adjacent a probe tip (18) having a rounded, closed end and multiple in-line orifices

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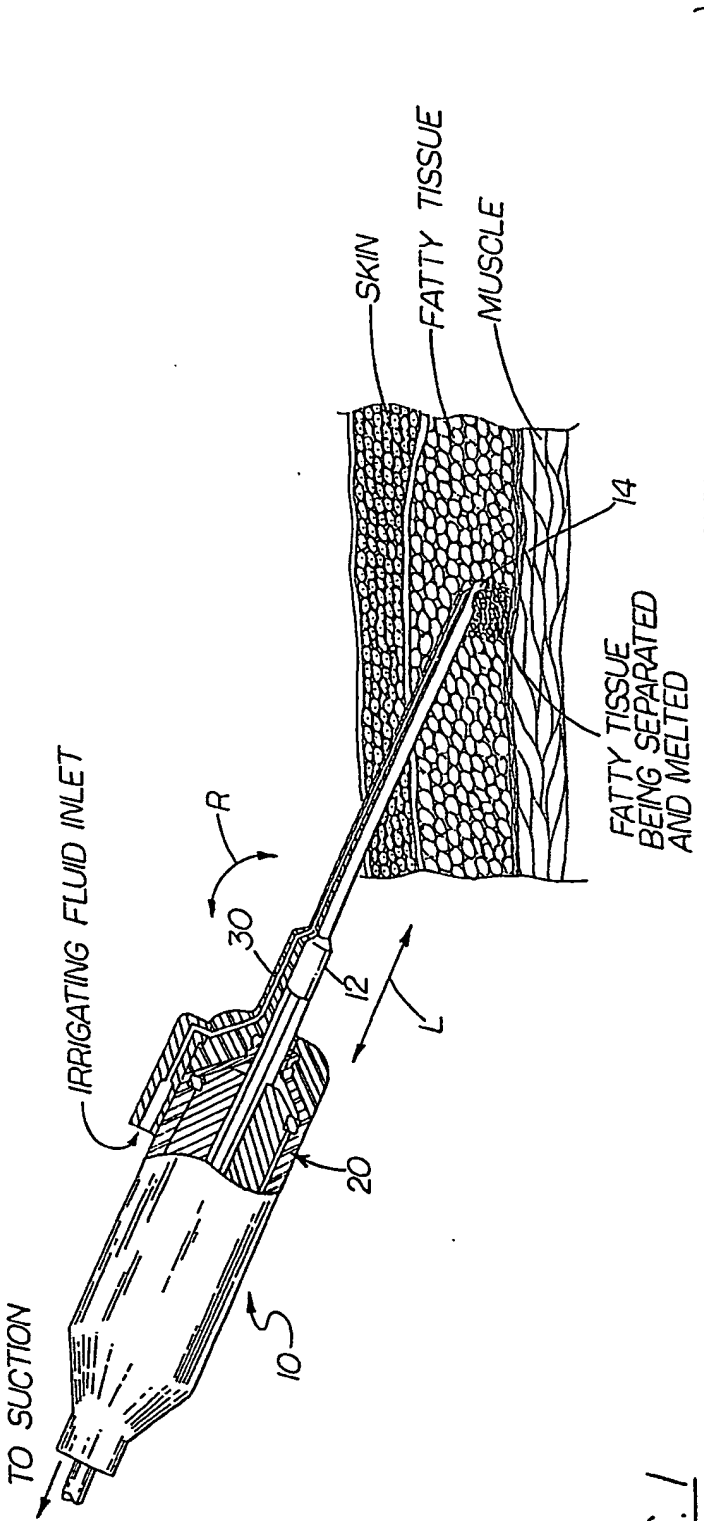

FIG. 1

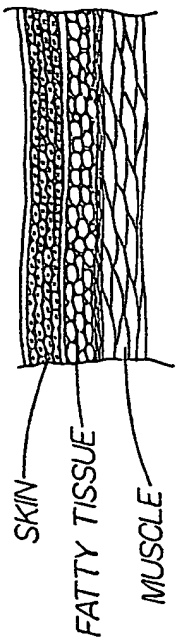

FIG. 2

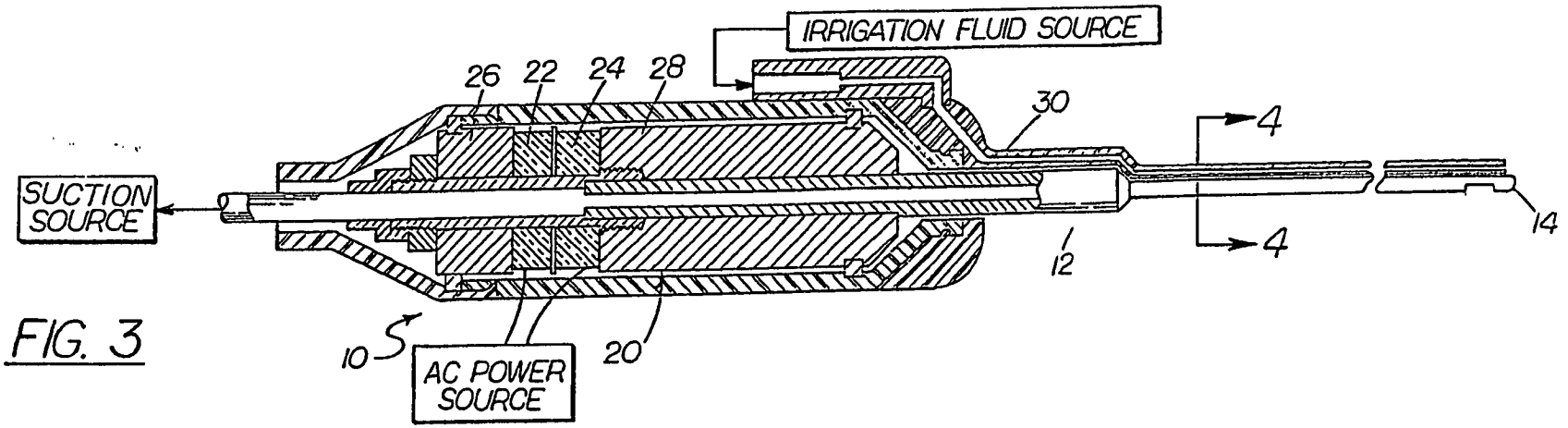

FIG. 3

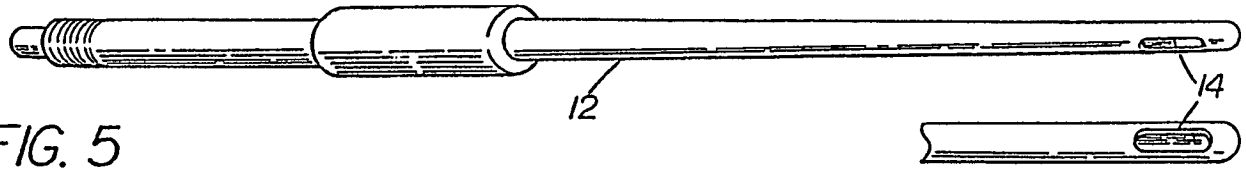

FIG. 5

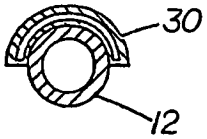

FIG. 4

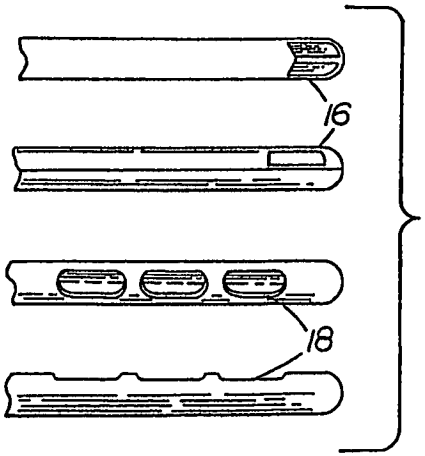

FIG. 6

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DECLARATION
which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application number
EP 89 30 1502

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of all claims.
Reason:

Method for treatment of the human or animal body by surgery or therapy (See art. 52(4) of the European Patent Convention)

CLASSIFICATION OF THE APPLICATION (Int. Cl.4)

A 61 M 1/00
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Place of search	Date of completion of the search	Examiner
The Hague	07-04-1989	VEREECKE